Environmental Protection Agency Office of Pesticide Programs



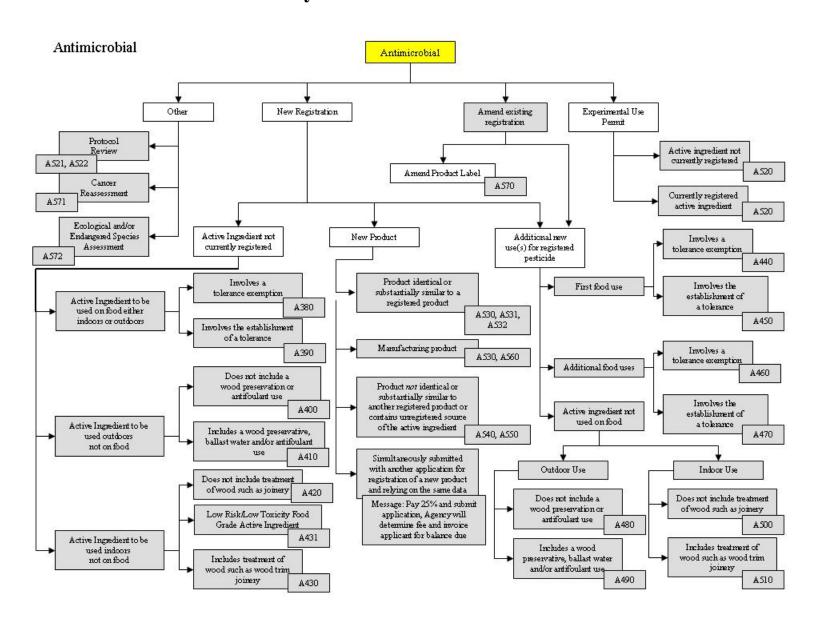
Fee Determination
Decision Tree Logic and Fees
For Fiscal Year 2008

Fee Determination Decision Tree Logic and Fees

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Pre-Pay Antimicrobial Decision Tree



Pre-Pay Antimicrobial - Action Codes and Fee Table

Antimicrobial Division (AD)

Action			
Code	Short Description	Fiscal Year	Fee
A380	Food use; establish tolerance exemption (1)	2008	\$94,500
A390	Food use; establish tolerance (1)	2008	\$157,500
A400	Non-food use; outdoor; FIFRA §2(mm) uses (1)	2008	\$78,750
A410	Non-food use; outdoor; uses other than FIFRA §2(mm) (1)	2008	\$157,500
A420	Non-food use; indoor; FIFRA §2(mm) uses (1)	2008	\$52,500
A430	Non-food use; indoor; uses other than FIFRA §2(mm) (1)	2008	\$78,750
A431	Non-food use; indoor; low-risk and low-toxicity food-grade active ingredient(s); efficacy testing for public health claims required under GLP and following DIS/TSS or AD-approved study protocol	2008	\$55,000
A440	First food use; establish tolerance exemption (1)	2008	\$26,250
A450	First food use; establish tolerance (1)	2008	\$78,750
A460	Additional food use; establish tolerance exemption	2008	\$10,500
A470	Additional food use; establish tolerance	2008	\$26,250
A480	Additional use; non-food; outdoor; FIFRA §2(mm) uses	2008	\$15,750
A490	Additional use; non-food; outdoor; uses other than FIFRA §2(mm)	2008	\$26,250
A500	Additional use; non-food; indoor; FIFRA §2(mm) uses	2008	\$10,500
A510	Additional use; non-food; indoor; uses other than FIFRA §2(mm)	2008	\$10,500
A520	Experimental Use Permit application	2008	\$5,250
A521	Review of public health efficacy study protocol within AD; per AD Internal Guidance for the Efficacy Protocol Review Process; applicant-initiated; Tier 1	2008	\$2,000
A522	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; applicant-initiated; Tier 2	2008	\$10,000
A530	New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; citeall data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix.	2008	\$1,050
A531	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner.	2008	\$1,500
A532	New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted	2008	\$4,200

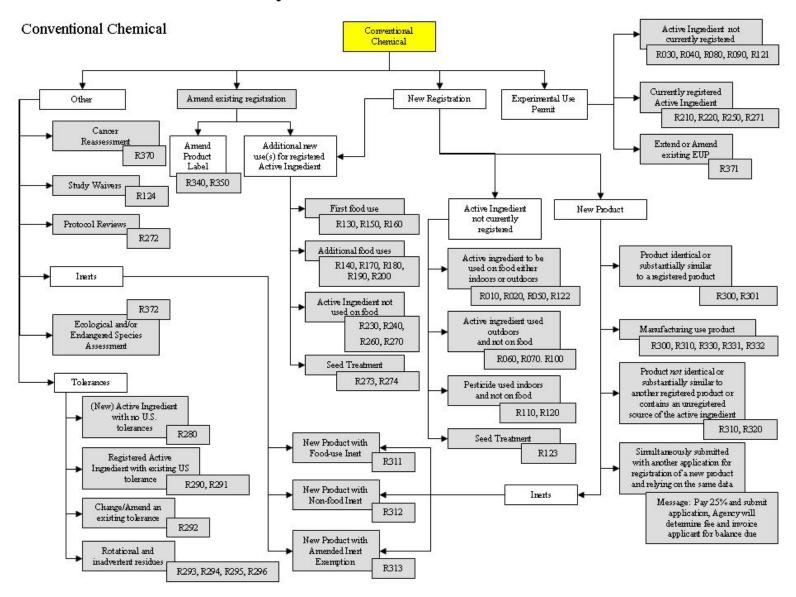
Pre-Pay Antimicrobial - Action Codes and Fee Table

Antimicrobial Division (AD)

Action			
Code	Short Description	Fiscal Year	Fee
A540	New end use product; FIFRA §2(mm) uses only	2008	\$4,200
A550	New end-use product; uses other than FIFRA §2(mm); non-FQPA product	2008	\$4,200
A560	New manufacturing-use product; registered active ingredient; selective data citation	2008	\$15,750
A570	Label amendment requiring data submission (2)	2008	\$3,150
A571	Cancer reassessment; applicant-initiated	2008	\$78,750
A572	Refined ecological risk and/or endangered species assessment; applicant-initiated	2008	\$75,000

- (1) All uses (food and/or non-food) included in any original application or petition for a new active ingredient or a first food use that otherwise satisfy the conditions for the category are covered by the base fee for that application.
- (2) EPA-initiated amendments shall not be charged fees. Fast-track amendments handled by the Antimicrobials Division are to be completed within the FIFRA stated timelines listed in Section 3(h) and are not subject to PRIA fees. Label amendments submitted by notification under PR Notices such as PR Notice 95-2 and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.

Pre-Pay Conventional Chemical Decision Tree



Action			
Code	Short Description	Fiscal Year	Fee
R010	Food use (1)	2008	\$516,300
R020	Food use; reduced risk (1)	2008	\$516,300
R030	Food use; Experimental Use Permit application submitted simultaneously with application for registration; decision time for Experimental Use Permit and temporary tolerance same as #R040 (1)	2008	\$570,700
R040	Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit \$326,025 toward new active ingredient application that follows	2008	\$380,500
R050	Food use; application submitted after Experimental Use Permit application; decision time begins after Experimental Use Permit and temporary tolerance are granted (1)	2008	\$190,300
R060	Non-food use; outdoor (1)	2008	\$358,700
R070	Non-food use; outdoor; reduced risk (1)	2008	\$358,700
R080	Non-food use; outdoor; Experimental Use Permit application submitted simultaneously with application for registration; decision time for Experimental Use Permit same as #R090 (1)	2008	\$396,800
R090	Non-food use; outdoor; Experimental Use Permit application submitted before application for registration; credit \$228,225 toward new active ingredient application that follows	2008	\$266,300
R100	Non-food use; outdoor; submitted after Experimental Use Permit application; decision time begins after Experimental Use Permit is granted (1)	2008	\$130,500
R110	Non-food use; indoor (1)	2008	\$199,500
R120	Non-food use; indoor; reduced risk (1)	2008	\$199,500
R121	Non-food use; indoor; Experimental Use Permit application submitted before application for registration; credit \$100,000 toward new active ingredient application that follows	2008	\$150,000
R122	Enriched isomer(s) of registered mixed-isomer active ingredient (1)	2008	\$260,900
R123	Seed treatment only; includes non-food and food uses; limited uptake into Raw Agricultural Commodities (1)	2008	\$388,200
R124	Conditional Ruling on Preapplication Study Waivers; applicant-initiated	2008	\$2,080
R130	First food use; indoor; food/food handling (1)	2008	\$157,500
R140	Additional food use; Indoor; food/food handling	2008	\$36,750
R150	First food use (1)	2008	\$217,400
R160	First food use; reduced risk (1)	2008	\$217,400

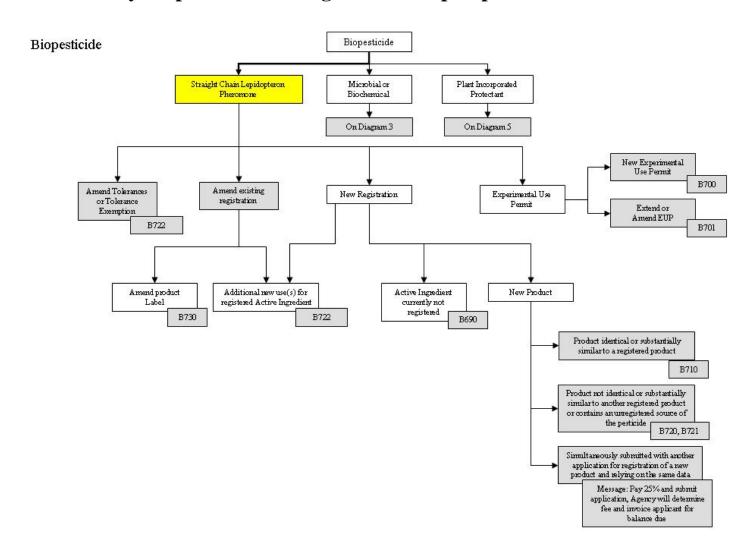
Action Code	Short Description	Fiscal Year	Fee
R170	Additional food use	2008	\$54,400
R180	Additional food use; reduced risk	2008	\$54,400
R190	Additional food uses; 6 or more submitted in one application	2008	\$326,400
R200	Additional food uses; 6 or more submitted in one application; reduced risk	2008	\$326,400
R210	Additional food use; Experimental Use Permit application; establish	2008	\$40,300
	temporary tolerance; no credit toward new use registration		
R220	Additional food use; Experimental Use Permit application; crop destruct	2008	\$16,320
	basis; no credit toward new use registration		
R230	Additional use; non-food; outdoor	2008	\$21,740
R240	Additional use; non-food; outdoor; reduced risk	2008	\$21,740
R250	Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration	2008	\$16,320
R260	New use; non-food; indoor	2008	\$10,500
R270	New use; non-food; indoor; reduced risk	2008	\$10,500
R271	New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration	2008	\$8,000
R272	Review of Study Protocol; applicant-initiated; excludes DART, pre- registration conferences, Rapid Response review, DNT protocol review, protocols needing HSRB review	2008	\$2,080
R273	Additional use; seed treatment; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food or non-food uses	2008	\$41,500
R274	Additional uses; seed treatment only; 6 or more submitted in one application; limited uptake into Raw Agricultural Commodities; includes crops with established tolerances (e.g., for soil or foliar application); includes food and/or non-food uses	2008	\$249,000
R280	Establish import tolerance; new active ingredient or first food use (1)	2008	\$262,500
R290	Establish import tolerance; additional food use	2008	\$52,500
R291	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition	2008	\$315,000
R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	2008	\$37,300
R293	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated	2008	\$44,000

Action Code	Short Description	Fiscal Year	Fee
R294	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated	2008	\$264,000
R295	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; applicant-initiated	2008	\$54,400
R296	Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; applicant-initiated	2008	\$326,400
R300	New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix.	2008	\$1,300
R301	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner.	2008	\$1,560
R310	New end-use or manufacturing-use product; requires review of data package within RD; includes reviews and/or waivers of data for only:	2008	\$4,360
	product chemistry and/or		
	acute toxicity and/or		
	public health pest efficacy		
R311	New product; requires approval of new food-use inert; applicant-initiated; excludes approval of safeners	2008	\$15,540
R312	New product; requires approval of new non-food-use inert; applicant-initiated	2008	\$8,300
R313	New product; requires amendment to existing inert tolerance exemption (e.g., adding post-harvest use); applicant-initiated	2008	\$11,420
R320	New product; new physical form; requires data review in science divisions	2008	\$10,880
R330	New manufacturing-use product; registered active ingredient; selective data citation	2008	\$16,320
R331	New product; repack of identical registered end-use product as a manufacturing-use product; same registered uses only	2008	\$2,080
R332	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new generic data package; registered uses only	2008	\$233,000

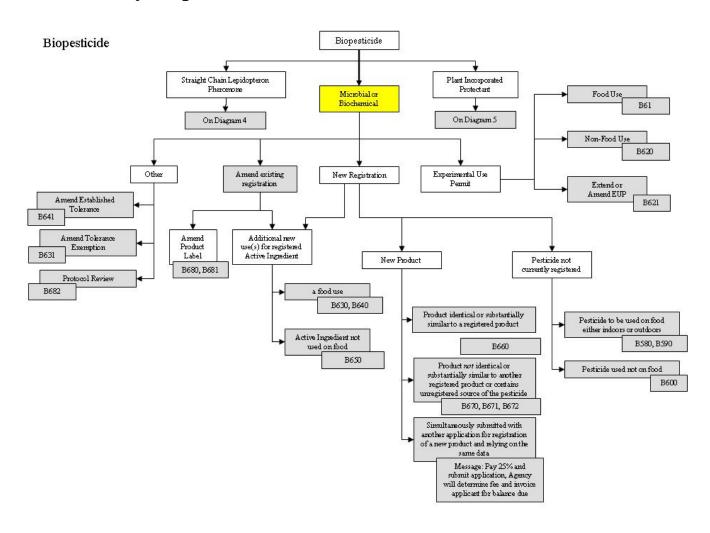
Action Code	Short Description	Fiscal Year	Fee
R340	Amendment requiring data review within RD (e.g., changes to precautionary label statements, or source changes to an unregistered source of active ingredient) (2)	2008	\$3,280
R350	Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement) (2)	2008	\$10,880
R370	Cancer reassessment; applicant-initiated	2008	\$163,100
R371	Amendment to Experimental Use Permit; requires data review / risk assessment	2008	\$8,300
R372	Refined ecological and/or endangered species assessment; applicant-initiated	2008	\$155,300

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- (2) EPA-initiated amendments shall not be charged fees. Fast-track amendments handled by the Antimicrobials Division are to be completed within the FIFRA stated timelines listed in Section 3(h) and are not subject to PRIA fees. Label amendments submitted by notification under PR Notices such as PR Notice 95-2 and PR Notice 98-10, continue under PR Notice timelines and are not subject to PRIA fees.

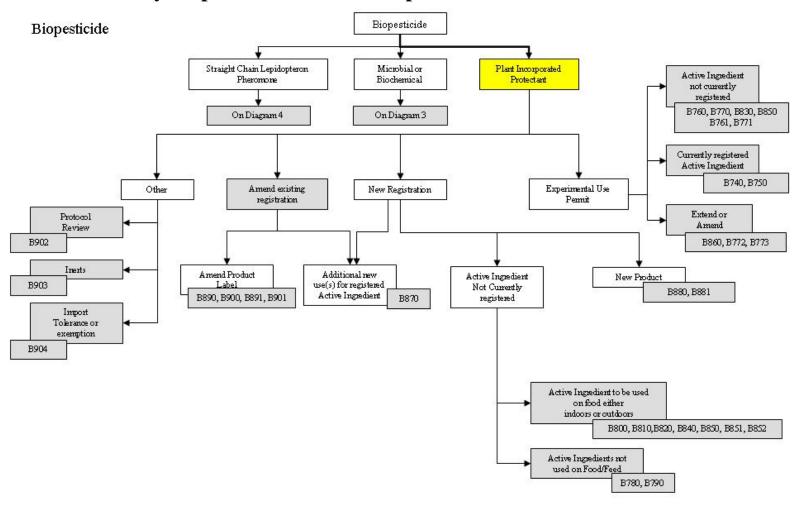
Pre-Pay Biopesticide – Straight Chain Lepidopteron Decision Tree



Pre-Pay Biopesticide – Microbial or Biochemical Decision Tree



Pre-Pay Biopesticide – **Plant Incorporated Protectant Decision Tree**



Action			
Action Code	Short Description	Fiscal Year	Fee
B580	New active ingredient; food use; establish tolerance (1)	2008	\$42,000
B590	New active ingredient; food use; establish tolerance exemption (1)	2008	\$26,250
B600	New active ingredient; non-food use (1)	2008	\$15,750
B610	Food use; Experimental Use Permit application; establish temporary tolerance exemption	2008	\$10,500
B620	Non-food use; Experimental Use Permit application	2008	\$5,250
B621	Extend or amend Experimental Use Permit	2008	\$4,200
B630	First food use; establish tolerance exemption	2008	\$10,500
B631	Amend established tolerance exemption	2008	\$10,500
B640	First food use; establish tolerance (1)	2008	\$15,750
B641	Amend established tolerance (e.g., decrease or increase)	2008	\$10,500
B650	New use; non-food	2008	\$5,250
B660	New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix.	2008	\$1,050
B670	New product; registered source of active ingredient; all Tier I data for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product specific data or with request for data waivers supported by scientific rationales	2008	\$4,200
B671	New product; food use; unregistered source of active ingredient; requires amendment of established tolerance or tolerance exemption; all Tier I data requirements for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product-specific data or with request for data waivers supported by scientific rationales	2008	\$10,500
B672	New product; non-food use or food use having established tolerance or tolerance exemption; unregistered source of active ingredient; no data compensation issues; all Tier I data requirements for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product-specific data or with request for data waivers supported by scientific rationales	2008	\$7,500

Action			
Code	Short Description	Fiscal Year	Fee
B680	Label amendment requiring data submission (2)	2008	\$4,200
B681	Label amendment; unregistered source of active ingredient; supporting data require scientific review	2008	\$5,000
B682	Protocol review; applicant-initiated; excludes time for HSRB review (pre application)	2008	\$2,000
B690	New active ingredient; food or non-food use (1)	2008	\$2,100
B700	Experimental Use Permit application; new active ingredient or new use	2008	\$1,050
B701	Extend or amend Experimental Use Permit	2008	\$1,050
B710	New product; identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix.	2008	\$1,050
B720	New product; registered source of active ingredient; all Tier I data for product chemistry, toxicology, non-target organisms, and product performance must be addressed with product specific data or with request for data waivers supported by scientific rationales	2008	\$1,050
B721	New product; unregistered source of active ingredient	2008	\$2,200
B722	New use and/or amendment to tolerance or tolerance exemption	2008	\$2,200
B730	Label amendment requiring data submission (2)	2008	\$1,050
B740	Experimental Use Permit application; registered active ingredient; non-food/feed or crop destruct basis; no SAP review required (3)	2008	\$78,750
B750	Experimental Use Permit application; registered active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required (3)	2008	\$105,000
B760	Experimental Use Permit application; new active ingredient; non-food/feed or crop destruct basis; SAP review required; credit \$78,750 toward new active ingredient application that follows	2008	\$131,250
B761	Experimental Use Permit application; new active ingredient; non-food/feed or crop destruct; no SAP review required; credit \$78,750 toward new active ingredient application that follows	2008	\$78,750

Action			
Code	Short Description	Fiscal Year	Fee
B770	Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance exemption; SAP review required; credit \$105,000 toward new active ingredient application that follows	2008	\$157,500
B771	Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance exemption; no SAP review required; credit \$105,000 toward new active ingredient application that follows	2008	\$105,000
B772	Amend or extend Experimental Use Permit; minor changes to experimental design; established temporary tolerance or tolerance exemption is unaffected	2008	\$10,500
B773	Amend or extend existing Experimental Use Permit; minor changes to experimental design; extend established temporary tolerance or tolerance exemption	2008	\$26,250
B860	Amend Experimental Use Permit; first food use or major revision of experimental design	2008	\$10,500
B780	New active ingredient; non-food/feed; no SAP review required (4)	2008	\$131,250
B790	New active ingredient; Non-food/feed; SAP review required (4)	2008	\$183,750
B800	New active ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; no SAP review required (4)	2008	\$210,000
B810	New active ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; SAP review required (4)	2008	\$262,500
B820	New active ingredient; establish tolerance or tolerance exemption; no SAP review required (4)	2008	\$262,500
B840	New active ingredient; establish tolerance or tolerance exemption; SAP review required (4)	2008	\$315,000
B830	New active ingredient; Experimental Use Permit application submitted simultaneously; establish tolerance or tolerance exemption; no SAP review required (4)	2008	\$315,000
B850	New active ingredient; Experimental Use Permit requested simultaneously; establish tolerance or tolerance exemption; SAP review required (4)	2008	\$367,500
B851	New active ingredient; different genetic event of a previously approved active ingredient; same crop; no tolerance action required; no SAP review required	2008	\$105,000
B852	New active ingredient; different genetic event of a previously approved active ingredient; same crop; no tolerance action required; SAP review required	2008	\$157,500

Action			
Code	Short Description	Fiscal Year	Fee
B870	New use (3)	2008	\$31,500
B880	New product; no SAP review required (5)	2008	\$26,250
B881	New product; SAP review required (5)	2008	\$78,750
B890	Amendment; seed production to commercial registration; no SAP review required	2008	\$52,500
B891	Amendment; seed production to commercial registration; SAP review required	2008	\$105,000
B900	Amendment (except #B890); No SAP review required; (e.g., new IRM requirements that are applicant initiated; or amending a conditional registration to extend the registration expiration date with additional data submitted) (2)	2008	\$10,500
B901	Amendment (except #B890); SAP review required (2)	2008	\$63,000
B902	PIP Protocol review	2008	\$5,250
B903	Inert ingredient tolerance exemption; e.g., a marker such as NPT II; reviewed in BPPD	2008	\$52,500
B904	Import tolerance or tolerance exemption; processed commodities/food only	2008	\$105,000

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- (3) Example: transfer existing PIP trait by traditional breeding, such as from field corn to sweet corn.
- (4) May be either a registration for seed increase or a full commercial registration. If a seed increase registration is granted first, full commercial registration is obtained using B890.
- (5) Example: Stacking PIP traits within a crop using traditional breeding techniques.